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510(k) SUMMARY (As Required per 21 CFR 807.92(c))

DEVICE OPERATION:

The Bovie IDS-400 (the **Generator**) operates by delivering high frequency radiofrequency (RF) energy which, when used in conjunction with other electrosurgical accessories, is used to cut and coagulate tissue. There is a characteristic electrical wave form associated with each mode. The electrical properties of the waveform (frequency and duration) produce the clinical effect (i.e. cut, coagulation). The shape and duration of waveforms are comparable between the generator and predicate devices.

The **Generator** functions in any of six user selectable modes:

Monopolar Cut I/II The cut modes allow the user to utilize electrosurgical current to vaporize or cut tissue.

Blend: The monopolar cutting speed and degree of hemostasis is controlled by the Monopolar blend control.

Coagulation (Pinpoint): Coagulation, also referred to as pinpoint coagulation, is used with forceps, blade, or needle electrodes and endoscopic devices. Coagulation is intended for use of small defined tissue areas. Coagulation is used to activate the generator prior to contacting tissue. Once the desired effect is achieved, the electrode is removed from the tissue area and deactivated. This coagulation mode provides precise control of bleeding in localized areas.

Fulguration (Spray Coagulation): Fulguration, also referred to as spray coagulation provides greater control of bleeding in highly vascularized tissues over broad surface areas. This mode is used with all types of pencil electrodes, endoscopic devices and clamps. Areas are repeatedly sprayed until desired hemostasis is established and can be used on all types of tissue.

Bipolar: The bipolar procedure is activated when performing coagulation with bipolar forceps.

The generator is designed to comply with applicable Medical Electrical Equipment safety standards, including electromagnetic compatibility and other safety standards.

The Generator uses technology substantially equivalent to the Aaron IDS-300 Electrosurgical Generator (K022856). There are no new hazards presented with the use of the Bovie IDS-400 Electrosurgical Generator as compared with the predicate device.

INTENDED USE:

The Bovie IDS-400 Electrosurgical Generator is a non-sterile, reusable multi-purpose electrosurgical generator that is designed to perform monopolar and bipolar functions in the operating arena.

510(k) SUMMARY (As Required per 21 CFR 807.92(c))

GENERAL INFORMATION:

510k Owner's Name **Address**	Bovie Medical 3200 Tyrone Boulevard, Suite A St. Petersburg, Florida 33710-2902
Contact Person	Richard A. Kozloff Vice-President; Quality Assurance/Regulatory Affairs Telephone #: (727) 803-8513 FAX Number: (727) 347-9144
Date Prepared:	July 23, 2007

DEVICE DESCRIPTION:

Trade Name:	Bovie IDS-400 Electrosurgical Generator
Common Name:	Electrosurgical Generator
Classification Name:	Electrosurgical Cutting and Coagulation Devices and Accessories (21CFR 878.4400; Class II; Product Code GEI)
Predicate Devices:	
Aaron Medical	IDS-300 High Frequency Electrosurgical Generator K022856

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2008

Bovie Medical
% Mr. Richard A. Kozloff
Vice President, Quality Assurance/Regulatory Affairs
3200 Tyrone Boulevard, Suite A
Saint Petersburg, Florida 33710-2902

Re: K072041
Trade/Device Name: Bovie IDS-400 Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: II
Product Code: GEI
Dated: March 31, 2008
Received: April 1, 2008

Dear Mr. Kozloff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072041

Device Name: Bovie IDS-400 Electrosurgical Generator

Indications for Use:

The Bovie IDS-400 Electrosurgical Generator is a non-sterile, reusable multi-purpose electrosurgical generator that is designed to perform monopolar and bipolar functions in the operating arena.

Prescription Use ✓ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072041